FORM PTO-1390 (REV 10-96) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: SCH 1637

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 09/091665

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DE96/02486	20 DECEMBER 1996	23 DECEMBER 1995

TITLE OF INVENTION: CONTRACEPTIVE PROCESS AND KIT FOR FEMALE MAMMALS THAT CONSISTS OF A COMBINATION OF GESTAGEN AND ESTROGEN

APPLICANT(S) FOR DO/EO/US: ENDRIKAT, Jan et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [ ] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [ ] Other items or information:

(January 1997)

US APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
	PCT/de96/02486	SCH 1637

17. [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		CALCULATIONS PTO USE ONLY
Search Report has been prepared by the EPO or JPO	$ 930.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482)	$ 720.00	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))	$ 790.00	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO	$ 1070.00	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)	$ 98.00	

ENTER APPROPRIATE BASIC FEE AMOUNT =				$ 930.00	
Surcharge of $130.00 for furnishing the oath or declaration later than [ ] 20 [XX] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				$ 130.00	
CLAIMS	NUMBER FILED		NUMBER EXTRA	RATE	
Total claims	12	- 20 =	0	X $ 22.00	$ 0.00
Independent claims	4	- 3 =	1	X $ 82.00	$ 82.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ $ 270.00	$
TOTAL OF ABOVE CALCULATIONS =					$ 1,142.00
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).					$
SUBTOTAL =					$ 1,142.00
Processing fee of $130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +					$
TOTAL NATIONAL FEE =					$ 1,142.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property +					$
TOTAL FEES ENCLOSED =					$ 1,142.00
				Amount to be: refunded	$
				charged	$

a. [XX] A check in the amount of $ 1,142.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-3402. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

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FILED: 22 June 1998

AJZ:lag

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REGISTRATION NUMBER

IN THE UNITED STATES DESIGNATED/ELECTED OFFICE

International Application No.	:	PCT/DE96/02486
International Filing Date	:	20 DECEMBER 1996
Priority Date Claimed	:	23 DECEMBER 1995
Applicant(s) (DO/EO/US)	:	ENDRIKAT, Jan et al.

Title: CONTRACEPTIVE PROCESS AND KIT FOR FEMALE MAMMALS THAT CONSISTS OF A COMBINATION OF GESTAGEN AND ESTROGEN

PRELIMINARY AMENDMENT

BOX PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

Prior to calculating the national fee, and prior to examination in the National Phase of the above-identified International application, please amend as indicated below.

IN THE CLAIMS:

Please **amend claims 3-5, and 10-12** as follows:

Claim 3, line 1: Delete "or 2".

Claim 4, line 1: Change "one of Claims 1 to 3" to -- Claim 1 --.

Claim 5, line 1: Delete "2 or 3,"

Claim 10, line 1: Delete "or 9".

Claim 11, line 1: Change "one of Claims 8 to 10" to -- Claim 8 --.

Claim 12, line 1: Change "one of Claims 8 to 10" to -- Claim 8 --.

REMARKS

The principal purpose of this Preliminary Amendment is to eliminate multiple dependencies in order to avoid extra fees.

Respectfully submitted,

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WO 97/23228 PCT/DE96/02486

CONTRACEPTIVE PROCESS AND KIT FOR FEMALE MAMMALS THAT CONSISTS OF A COMBINATION OF GESTAGEN AND ESTROGEN

This invention relates to a contraceptive process for female mammals that consists of at least 28 days of sequential administration of:

(a) a gestagen in an ovulation-inhibiting dose for at least 28 days, in combination with

(b) a natural estrogen for 5 to 10 days at the end of the sequential administration of at least 28 days.

Since the 1960's, hormonal contraceptives have been known as, on the one hand, so-called combination preparations and stepped preparations and, on the other hand, sequential preparations. All of these preparations inhibit ovulation and produce regular menstrual bleeding (withdrawal bleeding).

Most hormonal contraceptives contain an estrogen and a gestagen (Table 1).

The different types of hormonal contraceptives.

Name	Composition
Combination preparation (one-phase preparation) of a stepped combination preparation	Estrogen and gestagen
Sequential preparation	Estrogen (1st phase) and estrogen/gestagen (2nd phase)
Minipill	Gestagen
Postcoital pill	Estrogen and gestagen

Combination preparations are characterized by the fact that the dosages of the two hormonal components (estrogen/gestagen) remain the same. Combination preparations exhibit high contraceptive reliability owing to the simultaneous administration of the gestagen and estrogen components from the first day of administration. In all forms of the combination preparations, the ovulatory LH-apex is reliably suppressed in such a way that both ovulation and the formation of the corpus luteum are suppressed [Elstein, M. et al.: Studies on Low Dose Oral Contraceptives: Cervical Mucus and Plasma Hormone Changes in Relation to Circulating d-Norgestrel and 17-Ethinyl Estradiol Concentrations. Fertil. Sterl 27:892 (1976)]. The early secretory transformation of the poorly developed endometrium can lead to the occurrence of spotting (intracyclic menstrual

bleeding), especially during the initial cycles when the preparations are taken.

To keep the gestagen dose low, so-called stepped combination preparations were developed. In this case, a distinction is made between two-stage and three-stage preparations. The two-stage preparations are distinguished in that the administration of gestagen is subdivided into two phases. In the first phase (11 days), a lower gestagen dose than in the second phase, with the same estrogen dose, is administered. In the three-stage preparations, the principle of stepped combination preparations was further refined; this is a modification of the two-stage preparation. Here, the gestagen dose is divided into three phases: the first phase contains a small gestagen dose, which is increased during the following two phases, while the estrogen dose is either constant over all three phases or is increased during the second phase.

Sequential preparations are distinguished in that they contain a pure estrogen component in the first 7 to at most 11 days of use, and they contain a gestagen component only in the subsequent 10 to at most 14 days. The influence of these preparations on the endometrium comes very close to the physiological cycle-dependent hormonal influence. The contraceptive reliability of the typical sequential preparations is based in the first phase only on the gonadotropin-inhibiting action of the estrogen, while the gestagen that is additionally taken during the second phase is mainly used for secretory

transformation of the endometrium and for regular triggering of withdrawal bleeding.

Most oral contraceptives are administered over a period of 21 days, followed by 7 days of placebos or pill-free days, thus imitating a normal cycle.

In addition, pure gestagen preparations are known.

In early studies, it was shown that even very small doses of the gestagen chloromadinone acetate afforded contraceptive protection although ovulation is not always inhibited by the small gestagen dose [Martınez-Manautou, J., J. Giner-Velasquez, V. Gallegos-Cortès, J. Casasola, R. Aznar, H. Rudel: Fertility Control with Microdose of Progestogen. In C. Gual: Proc. VIth Pan-Amer. Conf. Endocr. Mexico City 1965. Exerpta Med. (Amst.) Int. Congr. Ser. No. 112, pp. 157-165; Rudel, H. W., J. Martinez-Manautou, M. Maqueo-Topete: The Role of Progesterogens in the Hormonal Control of Fertility. Fert. and Sterl. 16 (1965) 158-169].

The use of pure gestagen preparations for contraception became important again since it turned out that the estrogen component could be responsible for some undesirable accompanying phenomena (headache; nausea, weight gain, etc.) and mainly for dangerous complications such as thromboembolic diseases [Daniel, D. G., Campell, A. C. Turnbull: Perperalthromboembolism and Suppression of Lactation. Lancet 1967/II, 287-289].

Because of the low dosage, the pure gestagen preparations came to be called the minipill. The minipills that have been introduced to date are without exception derivatives of 19-

nortestosterone: norethisterone, lynestrenol, and levonorgestrel. In contrast to estrogen/gestagen preparations, minipills are administered without interruption with regard to the time of bleeding since it was assumed that the unreliability of previously known pure gestagen preparations could be remedied if the administration period was extended.

The previously described pure gestagen preparations have a contraceptive reliability that is not very high; this can be attributed to the fact that ovulation is not always inhibited in a regular manner [Vessey et al.: Progestogen-Only Oral Contraception. Findings in Large Prospective Study with Special Reference to Effectiveness, Brit. J. Family Planning, 292: 526-30 (1986)]. In general, it can thus be expected that the proportion of anovulatory cycles is only between 15% and 40% under the influence of these low-dose gestagens [Chi, I.: The Safety and Efficacy of Progestin-Only Oral Contraceptives. An Epidemiologic Perspective. Contraception 47 (1993) 1-21].

Patent Application EP A 0 491 443 discloses a pure gestagen preparation in which the gestagens desogestrel and 3-ketodesogestrel are administered in a daily dose of 70 to 80 μg. In almost all women, these dosages cause inhibition of ovulation.

If gestagens alone are administered in ovulation-inhibiting doses, there is the risk, however, of amenorrhea, and in the case of prolonged administration, additional symptoms of hypoestrogeneity may occur.

There is therefore a need to ensure the advantages of a pure gestagen preparation combined with more reliable cycle control and regular menstrual-like bleeding.

It has now been found, surprisingly enough, that the administration of a gestagen in an ovulation-inhibiting amount for at least 28 days in combination with the administration of a natural estrogen, at the end of the cycle for 10 to 5 days, ensures optimum cycle control and regular menstrual-like bleeding.

This object is achieved in the above-described contraceptive process.

In a preferred embodiment of the inventive process, the mammals are humans.

In a preferred embodiment, the administration of the gestagen is done orally, and the administration of the natural estrogen is done transdermally. In another preferred embodiment, the administration of the gestagen is done transdermally, and the natural estrogen is administered orally.

In another embodiment, the invention relates to a contraceptive kit that contains at least 28 daily dosage units with

(a) a first phase that consists of at least 18 to 23 first daily dosage units of a gestagen in an ovulation-inhibiting dose, and

(b) a second phase that consists of at least 5 to 10 second daily dosage units of a gestagen in an ovulation-inhibiting dose, in combination with a natural estrogen.

Preferably, in all embodiments of the invention, the gestagen is selected from the group of compounds:

gestodene,

progesterone,

levonorgestrel,

cyproterone acetate,

chloromadinone acetate,

drospirenone (dihydrospirorenone),

norethisterone,

norethisterone acetate,

norgestimate,

desogestrel,

3-ketodesogestrel,

dienogest

or a mixture thereof.

In a special embodiment, the gestagen is contained in a daily dosage of:

0.05-0.2 mg of levonorgestrel,

0.05-0.15 mg of gestodene

or a bioequivalent dosage of another gestagen.

In a special embodiment, the gestagen levonorgestrel is contained in a daily dosage of 0.1 mg or gestodene in a daily dosage of 0.075 mg.

The inventive process combines the advantages of pure gestagen administration with more reliable cycle control and regular menstrual-like bleeding.

The gestagen ensures the contraceptive action, while the endometrium is built up by the natural estrogen, and in each case there is menstrual-like bleeding at the end of the combination phase.

This regimen exhibits the following advantages compared to the previously known processes for oral contraception:

- Ovulation is effectively inhibited by a daily gestagen dose that is low but high enough.
- Good cycle control is ensured by the sequential administration of natural estrogen.
- Even for women in premenopause, this inventive contraceptive is well-tolerated owing to the use of a natural estrogen and yields positive effects, especially in bones.
- Good general compatibility and especially liver-compatibility are ensured by the use of natural estrogen.
- It results in significantly fewer ethinyl estradiol-related side-effects.

Examples:

Examples of the inventive contraceptive process

Example 1.

	10-day administration of 2.5 mg of estradiol per day
28-day administration of 0.1 mg of levonorgestrel per day	

Example 2.

	8-day administration of 2.5 mg of estradiol per day
28-day administration of 0.1 mg of levonorgestrel per day	

Example 3.

	10-day administration of 2.5 mg of estradiol per day
56-day administration of 0.1 mg of levonorgestrel per day	

Example 4.

	10-day administration of 2.5 mg of estradiol per day
84-day administration of 0.1 mg of levonorgestrel per day	

Example 5.

	10-day administration of 2.5 mg of estradiol per day
28-day administration of 0.075 mg of gestodene per day	

Example 6.

	8-day administration of 2.5 mg of estradiol per day
28-day administration of 0.075 mg of gestodene per day	

Example 7.

	10-day administration of 2.5 mg of estradiol per day
56-day administration of 0.075 mg of gestodene per day	

Example 8.

	10-day administration of 2.5 mg of estradiol per day
84-day administration of 0.075 mg of gestodene per day	

Other embodiments will emerge from the description of inventive activity.

Examples of the embodiment of the contraceptive kit

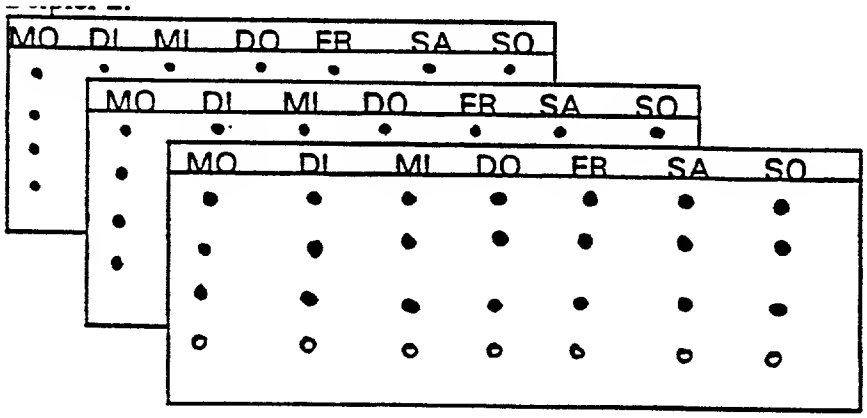
Example 1

MO	TU	WE	TH	FR	SA	SU
•	•	•	•	•	•	•
•	•	•	•	•	•	•
•	•	•	•	•	•	•
o	o	o	o	o	o	o

• = Gestagen-dosage unit (e.g., levonorgestrel 0.1 mg or gestodene 0.075 mg)

o = Gestagen- and estrogen-dosage unit (e.g., levonorgestrel 0.1 mg/estradiol 2.5 mg or gestodene 0.075 mg/estradiol 2.5 mg))

Example 2.



- • = Gestagen-dosage unit (e.g., levonorgestrel 0.1 mg or gestodene 0.075 mg)
- o = Gestagen- and estrogen-dosage unit (e.g., levonorgestrel 0.1 mg/estradiol 2.5 mg or gestodene 0.075 mg/estradiol 2.5 mg))

Other embodiments of the inventive kit can be ascertained from the description.

The administration of the inventive process can be done locally, topically, enterally, transdermally, or parenterally.

For the preferred oral administration, tablets, coated tablets, capsules, pills, suspensions, or solutions, which can be produced in the usual way with the additives and vehicles that are commonly used in galenicals, are especially suitable.

For local or topical use, for example, vaginal suppositories, vaginal gels, implants, vaginal rings, or transdermal systems such as skin patches are suitable.

If the administration of the inventive process is done by an implant, a vaginal ring, or a transdermal system, these administration systems must be constituted in such a way that each day they release the dose for the respective form of administration that is equivalent in action to the daily oral dose.

For transdermal administration by a skin patch, the following gestagens are especially suitable: gestodene, levonorgestrel, desogestrel, 3-ketodesogestrel or a mixture thereof, and as natural estrogens: estradiol at a concentration of 0.025-0.25 mg of release rate per day. The release rate per day for the gestagens that are to be administered transdermally

through a skin patch corresponds to the indicated daily dose concentrations.

The administration of the gestagen or the natural estrogen according to this invention can be done in such a way that both components are administered transdermally or else also that, for example, the gestagen is administered transdermally and the administration of the natural estrogen is done orally or, vice versa, the natural estrogen is administered transdermally and the gestagen orally.

The determination of equivalent-action doses of various gestagens and natural estrogens is done according to known methods; further details are found in, for example, the two articles "Probleme der Dosisfindung: Sexualhormone [Problems of Dose-Finding: Sex Hormones]"; F. Neumann et al., in "Arzneimittelforschung [Pharmaceutical Agent Research]" 27, 2a, 296-318 (1977) as well as "Aktuelle Entwicklungen in der hormonalen Kontrazeption [Current Developments in Hormonal Contraception]"; H. Kuhl in "Gynäkologe [Gynecology]" 25: 231-240 (1992).

Claims

1. Contraceptive process in female mammals that consists of at least 28 days of sequential administration of:

(a) a gestagen in an ovulation-inhibiting dose for at least 28 days in combination with

(b) a natural estrogen for 5 to 10 days at the end of the sequential administration of at least 28 days.

2. Contraceptive process in female mammals that consists of 28 days of sequential administration of:

(a) a gestagen in an ovulation-inhibiting dose for 28 days in combination with

(b) a natural estrogen for 5 to 10 days at the end of the sequential 28-day administration.

3. Process according to claim 1 or 2, in which the natural estrogen is administered for 10 days at the end of the sequential administration.

4. Process according to one of claims 1 to 3, in which the gestagen is selected from the group of compounds:

gestodene,

progesterone,

levonorgestrel,

cyproterone acetate,

chloromadinone acetate,

drospirenone (dihydrospirorenone),

norethisterone,

norethisterone acetate,

norgestimate,

desogestrel,

3-ketodesogestrel,

dienogest

or a mixture thereof.

5. Process according to claim 1, 2 or 3, in which the gestagen is contained in a daily dosage of:

0.05-0.2 mg of levonorgestrel,

0.05-0.15 mg of gestodene

or a bioequivalent dosage of another gestagen.

6. Process according to claim 1, whereby the administration of gestagen is done orally and/or transdermally.

7. Process according to claim 1, whereby the administration of natural estrogen is done orally and/or transdermally.

8. Contraceptive kit that contains at least 28 daily dosage units with

(a) a first phase that consists of at least 18 to 23 first daily dosage units of a gestagen in an ovulation-inhibiting dose, and

(b) a second phase that consists of at least 5 to 10 second daily dosage units of a gestagen in an ovulation-inhibiting dose, in combination with a natural estrogen.

9. Contraceptive kit that contains 28 daily dosage units with

(a) a first phase that consists of 18 to 23 first daily dosage units of a gestagen in an ovulation-inhibiting dose, and

(b) a second phase that consists of 5 to 10 second daily dosage units of a gestagen in an ovulation-inhibiting dose, in combination with a natural estrogen.

10. Contraceptive kit according to claim 8 or 9, in which the natural estrogen is administered for 10 days of the last third of the sequential administration.

11. Contraceptive kit according to one of claims 8 to 10, in which the gestagen is selected from the group of compounds:

gestodene,

progesterone,

levonorgestrel,

cyproterone acetate,

chloromadinone acetate,

drospirenone (dihydrospirorenone),

norethisterone,

norethisterone acetate,

norgestimate,

desogestrel,

3-ketodesogestrel,

dienogest

or a mixture thereof.

12. Contraceptive kit according to one of claims 8 to 10, in which the gestagen is contained in a daily dosage of:

0.05-0.2 mg of levonorgestrel,

0.05-0.15 mg of gestodene

or a bioequivalent dosage of another gestagen.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION

International Office

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(81) Designated countries: AL, AM, AU, AZ, BB, BG, BR, BY, CA, CN, CZ, EE, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, RO, RU, SD, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO Patent (KE, LS, MW, SD, SZ, UG), Eurasian Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European Patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published:

Without international search report and to be published again after receipt of the report.

(54) **Title:** CONTRACEPTIVE PROCESS AND KIT FOR FEMALE MAMMALS THAT CONSISTS OF A COMBINATION OF GESTAGEN AND ESTROGEN

(57) **Abstract**

This invention relates to a contraceptive process for female mammals that consists of at least 28 days of sequential administration of: (a) a gestagen in an ovulation-inhibiting dose for at least 28 days in combination with (b) a natural estrogen for 5 to 10 days at the end of the sequential administration of at least 28 days, as well as a contraceptive kit.

Docket No.
SCH 1637

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Contraceptive Process and Kit for Female Mammals, Comprising a Combination of Gestagen and Oestrogen

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on **20 December 1996** as United States Application No. or PCT International Application Number **PCT/DE96/02486**

and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
195 49 264.1	**Germany**	**23/12/1995**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Docket No.
SCH 1637

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Contraceptive Process and Kit for Female Mammals, Comprising a Combination of Gestagen and Oestrogen

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on **20 December 1996** as United States Application No. or PCT International Application Number **PCT/DE96/02486**

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Not Claimed
195 49 264.1	**Germany**	**23/12/1995**	☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	
			☐
(Number)	(Country)	(Day/Month/Year Filed)	

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)
(Application Serial No.)	(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Anthony J. Zelano (Reg. No. 27,969)
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